

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

ROBERT BURNS LOGAN Individually and  
on Behalf of all Others Similarly Situated,

Plaintiff,

v.

QRX PHARMA LTD., AND JOHN  
HOLADAY

Defendants.

No. 1 : 15 - cv - 4868

**CLASS ACTION COMPLAINT  
FOR VIOLATIONS OF FEDERAL  
SECURITIES LAWS**

JURY TRIAL DEMANDED

Plaintiff Robert Burns Logan (“Plaintiff” or “Logan”), by and through the undersigned attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff’s information and belief is based upon, among other things, counsel’s investigation, which includes, without limitation: (a) a review and analysis of regulatory filings made by QRx Pharma Ltd. (“QRx” or the “Company”) with the United States Securities and Exchange Commission (“SEC”); (b) a review and analysis of press releases and media reports issued and disseminated by QRx; and (c) a review of other publicly available information concerning QRx.

**SUMMARY OF THE ACTION AND OVERVIEW**

1. This is a federal securities class action on behalf of all persons or entities who purchased or otherwise acquired QRx American Depositary Receipts (“ADR”) between January 24, 2011 and April 23, 2014 inclusive (the “Class Period”). Plaintiff seeks to pursue remedies against QRx and its former Chief Executive Officer (“CEO”) John Holaday (“Holaday”) for violations of §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder.

2. QRx is a specialty pharmaceutical company headquartered in Australia that focuses its research and development on treatments of pain management. QRx's ADR securities trade over-the-counter in the United States under the ticker symbols QRXPY and QRXPK. Throughout its history, the Company's main products have been "Dual Opioid" drugs that combine two different opioid painkillers, which the Company claims provide effective analgesia while decreasing the frequency and severity of opioid-related side effects. For much of the Company's history, QRx's main experimental drug was Moxduo (morphine sulfate and oxycodone hydrochloride), which would have been the first combination drug product to contain two active opioid ingredients.

3. Throughout the Class Period, Defendants made materially false and misleading statements regarding Moxduo's approval in the United States. Specifically, Defendants made false and/or misleading statements concerning the efficacy and safety of Moxduo as well as sufficiency of the Company's studies for Moxduo and the likelihood of Food and Drug Administration ("FDA") approval. In addition, Defendants failed to disclose to investors that: (1) QRx had received a "no agreement letter" in 2011 in which the FDA stated that it did not agree with the design of QRx's study to get Moxduo approved; (2) the Company had to appeal an FDA rejection of Moxduo two separate times; and (3) that the Company used deceptively designed studies in an attempt to produce favorable test results.

4. On April 23, 2014, the FDA Center for Drug Evaluation and Research released a memorandum (the "FDA Memo") which again denied QRx's application for Moxduo. This release painted a very different picture of Moxduo's history than QRx had led investors to believe. For example, the FDA Memo disclosed that: (i) the FDA sent the Company the no agreement letter in 2011 stating that it did not agree with QRx's design of its study to obtain

approval for Moxduo; (ii) QRx had to appeal the FDA's rejection two separate times in 2011; and (iii) Moxduo studies were not showing safety or efficacy benefits and were otherwise deceptively presented in an attempt to achieve favorable results.

5. As a result of these disclosures, the price of QRx ADRs dropped over 83% on April 23, 2014.

6. As a result of Defendants' wrongful acts and omissions, QRx ADRs traded at artificially inflated prices during the Class Period, and Plaintiff and other Class members suffered significant losses and damages. Accordingly, Plaintiff hereby brings claims against QRx and its CEO John Holaday, who exercised significant control over the Company during the Class Period. Plaintiff's claims arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

#### **JURISDICTION AND VENUE**

7. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5). This Court has jurisdiction over the subject matter of this action pursuant to 28U.S.C. §1331 and §27 of the Exchange Act (15 U.S.C. §78aa).

8. Venue is proper in this District pursuant to 28 U.S.C. §1391(b) and §27(c) of the Exchange Act (15 U.S.C. §78aa(c)). Many of the acts complained of herein, including the dissemination of materially false and misleading statements and reports prepared by or with the participation, acquiescence, encouragement, cooperation, or assistance of Defendants occurred, at least in part, in this District. The Registration Statement associated with the ADRs was executed in this District. Additionally, the Company has consented to the jurisdiction of this Court in the Deposit Agreement that was entered into by QRx when issuing its ADRs. The

Deposit Agreement states, “The Company irrevocably agrees that any legal suit, action or proceeding against the Company brought by the Depositary or any Holder, arising out of or based upon this Deposit Agreement or the transactions contemplated hereby, may be instituted in any state or federal court in New York, New York.”

9. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

### **PARTIES**

10. Plaintiff Logan, as set forth in the accompanying certification, incorporated by reference herein, purchased QRx shares during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

11. Defendant QRx is an Australian corporation with principal executive offices located in Victoria, Australia.

12. Defendant Holaday, at all relevant times, served as the CEO and managing director of QRx until his resignation on May 3, 2014. Upon information and belief, Defendant Holaday resides Bethesda, Maryland.

13. Holaday, because of his positions with the Company, possessed the power and authority to control the contents of QRx press releases, and presentations to securities’ analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Holaday made specific false and misleading statements and/or reviewed and approved the Company’s reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had

the ability and opportunity to prevent their issuance or cause them to be corrected. Because of his positions and access to material non-public information available to him, Holaday knew that the adverse facts specified herein had not been disclosed to, and were being concealed from the public, and that the positive representations which were being made were then materially false and/or misleading.

14. Holaday's primary liability and controlling person liability arises from the following facts, among others: (a) he was a high-level executive at the Company during the Class Period and a member of the Company's management team, was involved in and had knowledge of the discussions with the FDA; (b) by virtue of his responsibilities and activities as a senior officer of the Company, was privy to and participated in the creation, development, and reporting of the Company's internal budgets, plans, projections, and/or reports; (c) he enjoyed significant personal contact and familiarity with other high level executives and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances and operations at all relevant times; and (d) he was aware of the Company's dissemination of information to the investing public and knew, and/or recklessly disregarded, that it was materially false and misleading.

## **SUBSTANTIVE ALLEGATIONS**

### **Regulatory Background**

15. QRx's Moxduo would have been the first combination drug product to contain two active opioid ingredients. In order to gain approval for such combination drugs, the FDA requires that the applicant performs a study which demonstrates that the combination of the drug provides a direct benefit over the individual components when those individual components are

employed at equivalently potent dosages. This benefit can be demonstrated by an applicant if the test shows either an improved efficacy, *i.e.* a synergistic effect, or a better safety profile.

16. The Company represented that if approved by the FDA, Moxduo would be prescribed for the treatment of moderate to severe acute pain, which constitutes a \$2.5 billion segment of the \$8 billion spent annually on prescription opioids in the United States. In the months leading up to this application, and in the months and years that followed, QRx touted its ability to get FDA approval and that the Moxduo trials and studies were demonstrating that the product was providing a synergistic effect and an improved safety profile when compared to the individual components employed at equivalently potent dosages.

**Materially False and Misleading  
Statements Issued During the Class Period**

17. On January 24, 2011, QRx issued a press release entitled *QRxPharma Initiates Phase 3 Comparative Safety Study of MoxDuo®IR*. The press release stated in relevant part:

Sydney, Australia and Bedminster, NJ (Vocus/PRWEB) January 24, 2011

QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today initiation of a Phase 3 trial (Study 022) to compare the tolerability and safety profile of MoxDuo IR to equi-analgesic doses of either morphine or oxycodone given alone. Specifically, the study compares the incidence level of the opioid-related adverse events of moderate to severe nausea, vomiting and dizziness and changes in respiratory function in patients with moderate to severe postoperative pain following bunionectomy surgery. The Company expects to complete dosing in Q2 CY2011. The results of the trial will form part of a Marketing Authorisation Application (MAA) filing scheduled for submission later this year for approval to market in Europe. Study results, when published in medical literature, may, in conjunction with other trial data, be a component of the promotional package following projected commercial launch of MoxDuo IR in the US and in Europe in 2012.

***“Every trial conducted to date has demonstrated the benefits of MoxDuo, achieving as good or better pain relief with fewer incidences of moderate to severe side effects when compared with morphine, oxycodone or Percocet®,”*** said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. ***“We expect this head-to-head comparison of MoxDuo IR versus***

*equi-analgesic doses of morphine and oxycodone will provide data confirming the competitive advantages of our product over current standards of care.”*

\* \* \*

MoxDuo IR targets the acute pain market, a \$2.5 billion segment of the over \$7 billion spent annually on prescription opioids in the US. In April 2010, the Company released results from a “combination rule” pivotal study (008) comparing the efficacy and safety profiles of MoxDuo IR against component doses of morphine and oxycodone alone for the management of moderate to severe post-operative pain following bunionectomy surgery. ***MoxDuo IR not only demonstrated a statistically superior analgesic effect compared to component doses of morphine ( $p=0.02$ ) and oxycodone ( $p=0.02$ ) but, also a favourable side effect profile despite delivering twice the opioid dose of its individual components. With this trial, combined with the recently completed total knee replacement study (009 – data to be reported shortly), the Company believes it has met the basic clinical data requirements for NDA filing in Q2 CY2011 as planned.***

18. On February 21, 2011, QRx issued a press release entitled *FDA Grants QRxPharma Pre-New Drug Application Meeting in March 2011*. The press release stated in relevant part:

QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the granting of a pre-New Drug Application (NDA) meeting with the United States Food and Drug Administration (FDA) and successful completion of its third pivotal Phase 3 registration trial (study 009) for immediate-release MoxDuo.

Designed to evaluate the analgesic efficacy and safety of MoxDuo, study 009 compared a flexible dose against a fixed low-dose regimen for managing moderate to severe pain following total knee replacement surgery (TKR). QRxPharma’s analysis of data indicate that patients in the flexible dose treatment group achieved statistically superior pain reduction ( $p<0.02$ ) compared to those receiving the lower dose. Side effects were similar to those observed in earlier MoxDuo studies. The pre-NDA meeting with the FDA is scheduled for 22 March 2011. At that meeting, the Company and the FDA will review the adequacy of QRxPharma’s planned NDA submission including efficacy and safety findings and statistical analyses from this study and earlier trials, as well as technical organisation and proposed data summarisation methods.

“This is a major milestone for QRxPharma. We not only achieved the primary analgesic endpoint, but also believe the basic clinical requirements for NDA filing have been satisfied. We can see the goal line,” said Dr. John Holaday, Managing Director and CEO, QRxPharma. “Our upcoming pre-NDA meeting with the FDA



will explore QRxPharma's regulatory strategy and provide preliminary feedback about the sufficiency of our studies to set the stage for MoxDuo approval."

19. On July 25, 2011, QRx issued a press release entitled *QRxPharma Announces A\$35 Million Capital Raising to Progress MoxDuo Formulations and Support Commercialisation of MoxDuo® IR*. The press release state in relevant part:

***QRxPharma intends to use the proceeds from the Placement and Rights Issue to progress MoxDuo® IR through FDA approval and commercialisation leading to product launch expected in 2012***, to progress the development of MoxDuo controlled release (CR) and to provide additional working capital. The capital raising also puts the Company in a strong financial position as it negotiates with potential partners.

As announced to ASX on Monday 18 July 2011, the Company achieved another significant milestone as it commenced filing its New Drug Application (NDA) with the United States Food and Drug Administration (FDA) for MoxDuo IR for the treatment of moderate to severe acute pain, a \$2.5 billion segment of the \$8 billion spent annually on prescription opioids in the U.S. QRxPharma's product pipeline also includes intravenous (IV) and CR formulations which are in earlier stages of clinical development.

QRxPharma CEO and Managing Director, Dr. John Holaday commented, ***"We continue to make significant progress towards commercialising MoxDuo IR, having just initiated our NDA filing with the FDA. With this capital raising, we are in an excellent position to further develop our portfolio of Dual Opioid® pain products as we await FDA feedback on our NDA over the coming year.*** These additional resources also place us in a solid position as we continue our partnering negotiations."

Dr. Peter Farrell, Chairman of QRxPharma, stated, ***"This capital raising will allow QRxPharma to further important milestones including the commercialisation of MoxDuo IR for acute pain management, as well as enabling significant progress with its MoxDuo CR formulation for chronic pain,*** which the Board believes will support partnering discussions and add significant shareholder value."

20. On August 21, 2011, QRx issued a press release entitled *QRxPharma Completes NDA Submission for MoxDuo® IR*. The press release stated in relevant part:

QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today submission of its New Drug Application (NDA) clinical data package to the United States Food and Drug Administration (FDA) for MoxDuo IR, an



immediate-release Dual Opioid® pain therapy comprised of a patented 3:2 fixed ratio combination of morphine and oxycodone. The NDA Chemistry, Manufacturing and Controls (CMC) module was submitted to the FDA on 18 July and is currently under review. The Company believes submission of the clinical data from MoxDuo IR's successful Phase 3 clinical program completes its NDA filing requirements; the FDA typically takes 10-12 months to review these applications. The NDA filing is the basis for US regulatory approval of MoxDuo IR for the treatment of moderate to severe pain, a \$2.5 billion segment of the \$8 billion spent annually on prescription opioids in the US.

“Since QRxPharma’s initial public offering in 2007, we have strived towards an aggressive commercialisation strategy for MoxDuo – one that streamlined development timelines, was capital efficient, demonstrated clinical advantages of the product, and set the stage for commercial benefits to the company,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “We are pleased to have met this significant NDA milestone in just four years, and look forward to the regulatory approval process that may enable product sales in 2012.”

This completed NDA submission is based on a full non-clinical, clinical and manufacturing program for MoxDuo IR, and is being filed under 505(b)(2) regulations wherein approval for a new drug may be expedited by citing historical published evidence supporting each of MoxDuo’s already approved components to supplement the data derived from the robust QRxPharma development program. Consistent with the United States Federal Code of Regulations and as agreed with the FDA, the Company previously initiated the NDA review process by filing its completed CMC module in July 2011.

The Company has requested a Priority (accelerated) FDA review for MoxDuo IR based on favourable clinical data from several head-to-head comparisons with morphine, oxycodone, Percocet® and placebo. To date, more than 700 patients have been treated with MoxDuo IR in seven clinical trials over the Company’s successful Phase 3 program. Clinical data have consistently demonstrated that MoxDuo IR achieves equal or better pain relief with fewer incidences of moderate to severe opioid related side effects compared to current standards of care.

21. On December 20, 2011, QRx issued a press release entitled *QRxPharma*

*Announces Strategic Partnership with Actavis*. The press release stated in relevant part:

SYDNEY and BEDMINSTER, N.J., Dec. 20, 2011 /PRNewswire/ -- QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today execution of a binding Letter of Intent (LOI) with Actavis Inc. for the formation of a strategic partnership to commercialise MoxDuo IR in the U.S. acute pain marketplace.

MoxDuo IR is a patented 3:2 ratio fixed dose combination of morphine and oxycodone. Actavis Inc. is a subsidiary of Actavis Group, hf a privately held company based in Europe with 10,000 employees and annual global sales in excess of EUR 1.8 billion. Actavis Group is the world's fourth largest generic pharmaceutical company with a growing franchise in branded products.

***The launch of MoxDuo IR in the U.S. is projected to occur in 3Q CY2012, and pre-launch preparations will begin immediately.***

\* \* \*

"We are delighted to announce our partnership with Actavis," said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma.

"After analysis of several other licensing proposals, it was clear Actavis was the strategic choice for QRxPharma. Actavis' experience in the manufacturing, distribution, marketing and sales of both patented and generic opioid products ***enabled a partnership structure with QRxPharma that will accelerate revenues and maximise shareholder value.*** In addition, the agreement offered by Actavis provided the most flexibility as it only covers the domestic U.S. market for MoxDuo IR with an option for MoxDuo CR and MoxDuo IV."

\* \* \*

***The Actavis strategic partnership is a validation of the MoxDuo technology platform. With this agreement, we move significantly closer to a successful launch of MoxDuo IR into the \$2.5 billion acute pain market, a segment of the \$8 billion spent annually on prescription opioids in the U.S.,***" said Holaday.

***"We have efficiently developed our acute pain product MoxDuo IR, had its application for registration accepted by the United States Food and Drug Administration (FDA), and received a PDUFA date of 25 June 2012 as the FDA target date for action on the approval of the MoxDuo IR NDA."***

22. On June 27, 2012, QRx issued a press release entitled *Complete Response Letter from FDA Regarding MoxDuo NDA*. The press release stated, in pertinent part:

QRxPharma Limited announced today the United States Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the MoxDuo New Drug Application (NDA) for the treatment of moderate to severe acute pain. The Company is presently considering its response to the requests for additional information with regard to the safety and effectiveness of MoxDuo and has been granted a meeting with the FDA to clarify the steps required for approval.

"We remain confident in MoxDuo as a potential therapeutic option for the millions of patients suffering from moderate to severe acute pain and will

continue our efforts to bring this therapy to market,” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma.

"While we are disappointed by the Complete Response Letter, we are supportive of QRxPharma's continued efforts to work with the FDA to fully address their questions in a timely manner," said Doug Boothe, Chief Executive Officer, Actavis Inc. Within ten months of receiving a New Drug Application the FDA must provide either a decision to approve or issue a complete response, which informs the submission sponsor of changes that must be made before its application can be approved.

23. On August 20, 2012, QRx issued a press release entitled *QRxPharma Reports Productive Meeting with FDA Regarding MOXDUO® NDA*. The press release stated, in relevant part:

Sydney, Australia and Bedminster, New Jersey – ***QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the United States Food and Drug Administration (FDA) clarified to Company representatives during a post submission review meeting the steps required for approval of immediate release MOXDUO. The FDA requested further information regarding data filed as part of the MOXDUO New Drug Application (NDA) and additional analysis of trials completed to date, including Study 022 which evaluated oxygen desaturation levels in patients receiving MOXDUO compared to those administered morphine or oxycodone alone at equi-analgesic doses. Oxygen desaturation is a medically important adverse event and a leading cause of death from high doses of opioids. "We were encouraged by our reception at the FDA; the Agency confirmed our Combination Rule Study (Study 008) satisfied efficacy requirements and there were no unexpected or problematic safety issues in any of the studies submitted as part of the MOXDUO NDA," said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. "Additionally, at the FDA's invitation, we agreed to submit more extensive information on Study 022 and believe the results of this study provide further safety data to support approval of MOXDUO."***

Analysis of Study 022 was completed after the MOXDUO NDA filing in August 2011, although early safety data were included in the 120-day update filed last December. Accordingly, additional efficacy and safety information from this study was of significant interest to the FDA.

***The Company is presently preparing an additional data package for review and is considering further strategies to optimally manage the regulatory process. QRxPharma believes that the review of additional data and subsequent refiling of the NDA could result in a positive decision from the FDA by mid-2013.***

24. On November 7, 2012, QRX issued a press release announcing the Company's annual meeting and containing the Chairman's Address. *QRxPharma 2012 Annual General Meeting*. The Chairman's Address stated, in pertinent part:

In June this year we received the disappointing news that the United States Food and Drug Administration (FDA) had issued a Complete Response Letter (CRL), advising that we were not successful with our initial NDA filing in obtaining FDA approval for MOXDUO.

While this turn of events took the Company's board and management – and shareholders – by surprise, we have since been encouraged by the outcomes of our subsequent dialogue with the FDA.

***At a post-submission review meeting with the FDA in August 2012 the steps needed for approval were clarified. Importantly, it was confirmed at this meeting that there were no unexpected or problematic safety issues in any of the studies submitted as part of the MOXDUO NDA.***

The FDA has requested further information regarding data filed as part of the MOXDUO NDA and additional analysis of trials completed to date, which were targeted to meet requirements for approvals in Europe and Australia. Of particular interest to the FDA were the results from Study 022, a study that compared respiratory depression for MOXDUO versus single equi-analgesic doses of morphine and oxycodone. ***This study indicated that MOXDUO resulted in less severe respiratory depression than either morphine or oxycodone given separately.***

***The next step for the Company is to refile its NDA with the additional data to address the FDA's requests, which we believe could result in a positive decision from the FDA during 2013.***

***Based on the dialogue that has taken place with the FDA, as part of this process, the Board and I remain confident that MOXDUO will receive approval. There is a strong precedent with drugs which receive a CRL response in the first instance and then go on to obtain approval.***

25. On August 28, 2013, QRx issued a press release entitled *QRxPharma Receives Complete Response Letter from FDA Regarding MoxDuo® NDA*. This press release stated, in pertinent part:

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the United States Food and Drug

Administration (FDA) has issued a Complete Response Letter (CRL) regarding the Company's MOXDUO New Drug Application (NDA) for the treatment of moderate to severe acute pain. ***The Company confirmed the issuance of the CRL was to allow time to submit and evaluate further information required for the FDA to fully consider the respiratory safety advantages of MOXDUO from Study 022.***

26. On October 9, 2013, QRx issued a press release entitled *QRxPharma Reports Positive Meeting with The FDA on MOXDUO®*. The press release stated in pertinent part:

QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the results of its meeting on October 3 with the United States Food and Drug Administration (FDA) to discuss the Company's MOXDUO New Drug Application (NDA). At the end-of-review meeting, the FDA provided the Company with a more complete understanding of their requirements for submission of the revised NDA and data validation documentation.

The FDA reaffirmed that the safety and efficacy of MOXDUO are not at question, and that the Company's presentation of the totality of the respiratory safety advantages to an Advisory Committee of experts would help guide their final decision. Accordingly, the FDA encouraged QRxPharma to submit its validated data and updated NDA. The Agency will then schedule an Advisory Committee meeting preceding a Prescription Drug User Fee Act (PDUFA) date six months following NDA resubmission.

The tone of the meeting with the FDA was cordial and constructive, providing clear recommendations on how we should revise our NDA and document our validated data from the respiratory safety Study 022," said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. "We are highly confident in the integrity of the data defining the respiratory safety advantages of MOXDUO, and are now completing the documents for refiling by mid-November 2013."

The revised NDA is the basis for recommencing the regulatory approval process for MOXDUO for the treatment of moderate to severe acute pain, a \$2.5 billion USD segment of the \$8 billion USD spent annually on prescription opioids in the United States. The revised NDA also serves as the regulatory foundation for submitting MOXDUO for approval in Europe, Australia, Canada and other markets in the upcoming months. Assuming approval, the Company anticipates that MOXDUO will be launched in the United States during 2014.

27. The statements referenced in ¶¶17-26 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operational, and compliance policies, which were known

to Defendants and/or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: 1) the FDA had sent the Company a no agreement letter in 2011 stating that it did not agree with QRx's design of its study to obtain approval for Moxduo; (ii) QRx had to appeal the FDA's rejection two separate times in 2011; and (iii) Moxduo studies did not demonstrate safety or efficacy benefits and were otherwise deceptively represented.

### **The Truth Finally Emerges**

28. On April 23, 2014, the FDA Center for Drug Evaluation and Research released a memorandum (the "FDA Memo") which again denied QRx's application for Moxduo. The FDA release painted a very different picture of Moxduo's history than QRx had led investors to believe.

29. Specifically, and contrary to Defendants' prior representations, the FDA Memo denying QRx's application for Moxduo's stated that: (i) the FDA sent the Company the no agreement letter in 2011 stating that it did not agree with QRx's design of its study to get Moxduo approved; (ii) QRx had to appeal the FDA's rejection two separate times in 2011; (iii) Moxduo studies were not showing safety or efficacy benefits and were otherwise deceptive in an attempt to produce favorable results.

30. Additionally, the final report of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) dated April 22, 2014 noted a number of findings by the AADPAC which supported the determination that MoxDuo studies did not show the safety or efficacy benefits claimed by the Company. Specifically, the final report noted in pertinent part:

**DISCUSSION:** Please discuss whether the overall opioid-related adverse event data provide evidence of clinically meaningful differences in safety between Moxduo and morphine and/or Moxduo and oxycodone.



**Committee Discussion:** Members of the committee restated concerns with the quality of data supporting a respiratory safety advantage when addressing the overall safety profile of Moxduo. One member stated that, among the many analyses conducted post-hoc, only the oxygen desaturation data suggested any safety advantage. Without confidence in the clinical significance of the oxygen desaturation data, the committee could not conclude a clinically meaningful difference in overall safety.

**VOTE:** Given the available safety data, has the Applicant provided evidence that Moxduo is safer than morphine and oxycodone when these drugs are used individually and at comparable doses?

**Vote Result:** Yes – 0 / No – 14 / Abstain – 0

**Committee Discussion:** The committee unanimously agreed that given the available safety data, the Applicant has not provided evidence that Moxduo is safer than morphine and oxycodone when these drugs are used individually and at comparable doses. The committee members again cited insufficient evidence to determine a safety benefit for Moxduo. Members reiterated discomfort with the large number of post-hoc analyses, and the lack of a consistent signal of benefit among the resultant data. Please see the transcript for details of the committee discussion.

**VOTE:** Should Moxduo be approved for the management of moderate to severe acute pain where the use of an opioid analgesic is appropriate?

a. **DISCUSSION:** If you voted “No” to question #4, please discuss whether there are any additional studies to support approval of this product in the future.

**Vote Result:** Yes – 0 / No – 14 / Abstain – 0

**Committee Discussion:** The committee unanimously agreed that Moxduo should not be approved for the management of moderate to severe acute pain where the use of an opioid analgesic is appropriate. The position of the committee was summarized by the Chair, in reiterating the committee’s lack of confidence with any clinically meaningful safety difference, combined with the consensus from the sponsor and the agency that there is no notable efficacy difference. Given this lack of efficacy benefit and uncertain safety benefit, the Chair stated that there is “no basis for approval.”

31. As a result of these disclosures the price of QRx ADRs dropped over 83% on April 23, 2014 – from a prior opening price of \$3.40 to \$0.42 per share on unprecedented volume.



32. On May 2, 2014, QRx issued a press release stating that Holaday had stepped down as Managing Director and Chief Executive Officer of the Company.

33. On July 9, 2014, the Company announced that its Chairman of the Board, Dr. Peter Farrell, and Directors Dr. Gary Pace, Peter Campbell, and Michael Quinn resigned from the QRx Board.

34. Subsequently, on August 14, 2014, the Company announced that it was halting further development work on the MoxDuo portfolio of products. Specifically, the Company issued a press release which stated in pertinent part:

The management team has since conducted a detailed review of the MoxDuo technology with particular emphasis on the EOR meeting with the FDA and made a recommendation to the Board to halt all further development of the Moxduo IR, CR and IV programs. The Board of QRxPharma has agreed with, and accepted this recommendation.

The Company believes that the Moxduo program will require a repeat Phase 2 clinical study, followed by one or more pivotal Phase 3 clinical studies. The FDA has advised that agreement on a Special Protocol Assessment (SPA) would be unlikely for these studies and given specific issues related to the design of these clinical studies, such as a primary endpoint of 90% SpO2 and flexible dosing, both which have been strongly encouraged by FDA, the likelihood of success is now in considerable doubt.

The Company estimates the time and cost for such a development program to be significant and is not commercially justified given the limited residual patent life.

### **CLASS ACTION ALLEGATIONS**

35. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of all persons or entities who purchased or otherwise acquired QRx securities from January 24, 2011 to April 23, 2014 inclusive.

36. Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal

representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

37. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by QRx or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

38. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law, which is complained of herein.

39. Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

40. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of QRx;

(c) whether the price of QRx shares were artificially inflated during the Class Period; and

(d) to what extent the members of the Class have sustained damages and the proper measure of damages.

41. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

### **LOSS CAUSATION**

42. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

43. During the Class Period, Plaintiff and the Class purchased QRx shares at artificially inflated prices and were damaged thereby. When the misrepresentations that had been made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, the price of the Company's securities significantly declined, causing investors' losses.

### **APPLICABILITY OF PRESUMPTION OF RELIANCE**

#### **(FRAUD-ON-THE-MARKET DOCTRINE)**

44. QRx shares traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities,

relying upon the integrity of the market price of QRx shares and the market information relating to QRx, and have been damaged thereby.

45. During the Class Period, the artificial inflation of QRx shares was caused by the material misrepresentations and/or omissions particularized in this Complaint, causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about QRx's business, operations, and financial prospects. These material misstatements and/or omissions created an unrealistically positive assessment of QRx and its business, and financial condition, thus causing the price of the Company's securities to be artificially inflated at all relevant times and, when truthful information was disclosed, negatively affected the value of the Company ADRs. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices and being damaged as a result.

46. At all relevant times, the market for QRx securities was an efficient market for the following reasons, among others:

- (a) QRx ADRs met the requirements for listing, and was listed and actively traded over the counter;
- (b) as a regulated issuer in Australia, QRx filed periodic public reports with regulators; and
- (c) QRx regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the

national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services.

47. As a result of the foregoing, the market for QRx securities promptly digested current information regarding QRx from all publicly available sources and reflected such information in QRx's ADR price. Under these circumstances, all purchasers of QRx securities during the Class Period suffered similar injury through their purchase of QRx securities at artificially inflated prices, and a presumption of reliance applies.

#### **NO SAFE HARBOR**

48. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made, and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of the forward-looking statements was made, the speaker had actual knowledge, or was reckless in not knowing, that the forward-looking statement was materially false or misleading and/or the forward-looking statement was authorized or approved by an executive officer of QRx who knew, or was reckless in not knowing, that the statement was false when made.

**COUNT I**

**Violation of §10(b) of the Exchange Act and Rule 10b-5 Promulgated  
Thereunder Against Defendants**

49. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

50. During the Class Period, the Defendants carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase QRx securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, the Individual Defendants took the actions set forth herein.

51. The Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for QRx securities in violation of §10(b) of the Exchange Act and Rule 10b-5. The Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

52. The Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mail, engaged and participated in a continuous course of conduct to conceal adverse material information about QRx's business, operations, and financial performance and prospects, as specified herein.

53. The Defendants employed devices, schemes, and artifices to defraud while in possession of material adverse non-public information and engaged in acts, practices, and a

course of conduct as alleged herein in an effort to assure investors of QRx's value, performance, and continued substantial growth. These acts included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about QRx and its business, operations, and financial prospects in light of the circumstances under which they were made, not misleading. As set forth more particularly herein, Defendants further engaged in transactions, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and disclose such facts, even though such facts were available to them. Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing QRx's financial condition from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' misstatements and/or omissions concerning the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

54. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of QRx securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by the Defendants, or upon the integrity of the market



in which the securities trade, and/or in the absence of material adverse information that was known to or recklessly disregarded by the Defendants, but not disclosed in public statements by the Defendants during the Class Period, Plaintiff and the other members of the Class acquired QRx securities during the Class Period at artificially high prices and were damaged thereby.

55. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding QRx and its business and prospects, which was not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their QRx securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices that they paid.

56. By virtue of the foregoing, the Defendants have violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

57. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

## **COUNT II**

### **Violation of §20(a) of the Exchange Act Against the Defendant Holaday**

58. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

59. Defendant Holaday acted as a controlling person of QRx within the meaning of §20(a) of the Exchange Act as alleged herein. By virtue of his high-level position, ownership and contractual rights, participation in and/or awareness of the Company's operations, and/or

intimate knowledge of the false statements filed by the Company with the SEC and disseminated to the investing public, Defendant Holaday had the power to influence and control, and did influence and control, directly or indirectly, the decision making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Defendant Holaday was provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

60. In particular, Defendant Holaday had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

61. As set forth above, QRx and Holaday violated §10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of his position as a controlling person, Defendant Holaday is liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of Defendant Holaday's wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure with Plaintiff serving as class representatives;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: June 23, 2015

**SCOTT+SCOTT, ATTORNEYS AT LAW, LLP**

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*Counsel for Plaintiff Logan*

**PLAINTIFF CERTIFICATION  
PURSUANT TO FEDERAL SECURITIES LAWS**

1. I, Burns Logan, ("Plaintiff"), make this declaration pursuant to Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act"), as amended by the Private Securities Litigation Reform Act of 1995.
2. I have reviewed the Complaint against QRX Pharma. ("QRX" or the "Company") and authorize the filing of a complaint on my behalf.
3. I did not purchase or acquire QRX securities at the direction of Plaintiff's counsel, or in order to participate in any private action arising under the Exchange Act.
4. I am willing to serve as a representative party on behalf of a class of investors who purchased or acquired QRX during the class period, including providing testimony at deposition and trial, if necessary.
5. My transaction(s) in QRX (**QRXPY**) that is the subject of this action during the Class Period is/are as follows:

<u>No of Shares</u>	<u>Buy/Sell</u>	<u>Date</u>	<u>Price Per Share</u>
57	Buy	2/16/2012	\$8.622807

6. During the prior three-year period preceding the date on which this Certification is signed, I have not sought to serve, or served, as a class representative in a federal securities fraud case.
7. I agree not accept any payment for serving as a representative party on behalf of the class beyond my pro rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.
8. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 8<sup>th</sup> day of June, 2015, at Englewood, Colorado (city, state).

Signature:



Your Printed Name:

Robert Burns Logan